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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/755,017 | 01/05/2001 | D. Wade Walke | LEX-0115-USA | 4534 |

24231 7590 03/15/2004

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| EXAMINER | |
|---|---|
| BUNNER, BRIDGET E | |
| **ART UNIT** | **PAPER NUMBER** |
| 1647 | |

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/755,017 | WALKE ET AL. | |
| | Examiner | Art Unit | |
| | Bridget E. Bunner | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Prosecution Application*

The Request for Continued Examination (RCE) filed on 29 September 2003 under 37 CFR 1.114 based on parent Application No. 09/755,017 is acceptable and an RCE has been established. An action on the RCE follows.

### *Status of Application, Amendments and/or Claims*

The amendment of 29 September 2003 has been entered in full. Claims 5 and 7 are amended and claims 1-2 are cancelled. Claim 9 is added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3-9 are under consideration in the instant application.

### *Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph*

1. Claims 3-9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation. The basis for this rejection is set forth for claims 1-8 at pages 2-14 of the previous Office Action (23 October 2003).

Specifically, the claims recite an isolated nucleic acid molecule comprising the nucleic acid sequence presented in SEQ ID NO: 1. The claims also recite an isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2. Additionally, the claims are directed to expression vectors and host cells comprising the nucleic acid molecules. Claim 9 is directed to an isolated nucleic acid molecule encodes

SEQ ID NO: 2 and hybridizes under stringent conditions with wash conditions of 0.1xSSC/0.1% SDS at 68°C to the nucleotide sequence of SEQ ID NO: 1.

Applicant's arguments (29 September 2003), as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

(i) At page 4 of the Response, Applicant asserts that the amino acid sequence of the GPCR of the present invention is identical to SwissProt Accession No. P58173 (gi 14423785), human olfactory receptor 2B6, as shown in Exhibit A. Applicant indicates that as this protein was annotated by those of skill in the art in no way associated with Applicant, Applicant's assertion regarding the function and utility of the protein of the present invention is credible.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant asserts that the NGPCR protein (SEQ ID NO: 2) of the instant application is homologous to existing G protein coupled receptors, specifically odorant receptors. However, Ji et al. (J Biol Chem 273(28): 17299-17302, 1998) indicate that G protein coupled receptors are classified into over 100 subfamilies according to sequence homology, ligand structure, and receptor function. A substantial degree of amino acid homology is found among members of a particular subfamily, but comparisons between subfamilies show significantly less or no similarity. Mutant G protein coupled receptors are incapable of binding ligand or generating normal signals, constitutively generate signals, or are not appropriately expressed on the cell surface (pg 17299, pp 1-2). Also, "an increasing number of G protein coupled receptor subfamilies show diverse modes of ligand binding, signal generation, transmembrane signal transduction, and signal transfer to various cytoplasmic signal molecules other than G protein" (pg 17302, pp 4). Furthermore, since the specification does not disclose any methods or working

examples that demonstrate the NGPCR polynucleotide and polypeptide of the instant application exhibit similar activities of other G-protein coupled receptors, particularly odorant receptors, the skilled artisan would not be able to categorize the polynucleotide and polypeptide of the instant application as a G-protein coupled receptor. Additionally, the specification of the instant application does not teach the skilled artisan which domains of the NGPCR polynucleotide and polypeptide are structurally characteristic of G protein-coupled receptors. One skilled in the art would not know the utility and function of NGPCR (SEQ ID NO: 2), even if it was a putative G protein coupled receptor because, as discussed in the related art above, G protein coupled receptors include a wide range of biologically active receptors, and neither the prior art nor the specification provides for the physiological significance of the disclosed and claimed receptor.

It is noted to Applicant that the specification of the instant application does not disclose that the claimed polynucleotide of SEQ ID NO: 1 or the polypeptide of SEQ ID NO: 2 are specifically homologous to *odorant/olfactory* receptors. Furthermore, the human olfactory receptor 2B6 (Hs6m1-32), which Applicant asserts the polypeptide of the instant application is 100% homologous to, has not been well characterized in the art as an odorant receptor. Since the human olfactory receptor 2B6 has no functional or structural characteristics described in the art, the polypeptide of SEQ ID NO: 2 of the instant application has no credible, specific and substantial asserted utility or a well established utility.

Furthermore, the assertion that the disclosed NGPCR polynucleotides and polypeptides have biological activities similar to known odorant/olfactory receptors cannot be accepted in the absence of supporting evidence, because the relevant literature reports examples of polypeptide families wherein individual members have distinct, and sometimes even opposite, biological

activities. For example, Tischer et al. (U.S. Patent 5,194,596) establishes that VEGF (a member of the PDGF, or platelet-derived growth factor, family) is mitogenic for vascular endothelial cells but not for vascular smooth muscle cells, which is opposite to the mitogenic activity of naturally occurring PDGF which is mitogenic for vascular smooth muscle cells but not for vascular endothelial cells (column 2, line 46 to column 3, line 2). The differences between PDGF and VEGF are also seen *in vivo*, wherein endothelial-pericyte associations in the eye are disrupted by intraocular administration of PDGF but accelerated by intraocular administration of VEGF (Benjamin et al., 1998, Development 125:1591-1598; see Abstract and pp. 1594-1596). In the transforming growth factor (TGF) family, Vukicevic et al. (1996, PNAS USA 93:9021-9026) disclose that OP-1, a member of the TGF-β family of proteins, has the ability to induce metanephrogenesis, whereas closely related TGF-β family members BMP-2 and TGF-β1 had no effect on metanephrogenesis under identical conditions (p. 9023, paragraph bridging columns 1-2). See also Massague, who reviews other members of the TGF-β family (1987, Cell 49:437-8, esp. p. 438, column 1, second full paragraph to the end). Similarly, PTH and PTHrP are two structurally closely related proteins which can have opposite effects on bone resorption (Pilbeam et al., 1993, Bone 14:717-720; see p. 717, second paragraph of Introduction). Finally, Kopchick et al. (U.S. Patent 5,350,836) discloses several antagonists of vertebrate growth hormone that differ from naturally occurring growth hormone by a single amino acid (column 2, lines 37-48).

Additionally, according to MPEP 2107, in order for Applicant to rebut the rejection for lack of utility imposed because the invention lacks an asserted specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility, Applicant must provide evidence that one of ordinary skill in the art would have recognized that the

identified specific and substantial utility was well-established at the time of filing. In the instant case, even if the receptor 2B6 (Hs6m1-32) polypeptide (P58173) is found to function as an olfactory receptor, the date of publication of the sequence is October 2001, which is after the filing date of the instant application. In order for an asserted utility to be well-established, it must be well-established at the time of filing. Since the olfactory receptor 2B6 polypeptide is a post-filing reference, the asserted utility was not well-established at the time of filing.

Further according to MPEP 2107, the examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention. In the instant case, at the time of filing the instant nucleic acids were not disclosed as encoding specifically olfactory receptors, but only described as encoding generically as G protein coupled receptors (see specification pg 2, lines 5-15). G protein coupled receptors include a wide range of biologically active receptors. The fact that the specification only describes the encoded polypeptide as a G protein coupled receptor demonstrates that at the time of filing, Applicant did not know the type of receptor, if any, the encoded polypeptide would make. Since the originally disclosed properties of the claimed invention are only set forth as encoding a G protein coupled receptor, there is not a probative relationship between the submitted evidence of the encoded polypeptide allegedly functioning as an olfactory receptor, and the disclosed properties of the encoded polypeptide being a G protein coupled receptor.

However, as noted above, the annotation of the P58173 polypeptide sequence as an olfactory receptor was published post-filing, and thus the utility was not well-established at the

time of filing, and furthermore, there is not a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention, since the encoded polypeptide was only described as a G protein coupled receptor, not an olfactory receptor. In addition, it is not clear that the P58173 polypeptide was ever demonstrated to be an olfactory receptor. Thus, while Applicant is relying on P58173 (olfactory receptor 2B6) to show the utility of the claimed encoding polynucleotide, it is not clear that the function of P58173 (olfactory receptor 2B6) is actually known.

(ii) At the top of pg 5 of the Response, Applicant contends that there can be no question that those skilled in the art recognize the pharmaceutical utility of GPCR proteins because over half of the current drugs on the market address GPCR proteins. Applicant argues that multiple millions of dollars are allocated yearly in the identification and targeting of G-protein coupled receptors, such as those of the present invention. Applicant states that if these molecules did not have well established utility recognized by those of skill in the art in the pharmaceutical industry, those in such a competitive industry would not direct so much of their limited resources towards this class of receptors. At pg 8 of the Response, Applicant states that persons of skill in the art, as well as thousands of venture capitalists and investors, readily recognize the utility, both scientific and commercial, of genomic data, specifically human genomic data. Applicant argues that billions of dollars have been invested in the human genome project, resulting in useful genomic data. Applicant asserts that the usefulness of human genomic data, such as the presently claimed nucleic acid molecules, is substantial and credible and well established.

Commercial success is not necessarily evidence of patentable utility. Commercial success requires more than the mere sale of a compound. Commercial success is discussed in the MPEP at 716.03 is applicable to obviousness rejections, but is not a valid consideration for utility which requires specific, substantial and credible utility. Applicant also has not established a nexus between the *claimed* invention and evidence of commercial success. Furthermore, the sale of a compound is not evidence of commercial success and sale of a compound for use as a scientific tool does not appear to be a specific, substantial and credible utility as set forth in the "REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS".

(iii) Applicant asserts at page 5-6 of the Response that methods similar to those of the present invention were used to identify the GPCR of issued U.S. patent 6,043,052. Applicant contends that issued U.S. patents are presumed to valid and to meet the requirements of 35 U.S.C. § 101, 102, 103, and 112, specifically, that they have utility, are novel, non-obvious, are enabled, meet written description requirements and particularly point out and distinctly claim the invention. Applicant submits that the GPCR of the instant application is in fact supported by issued U.S. Patent 6,043,052 as well as the plethora of other GPCR patents that the office has issued. Applicant argues that the issuance of other U.S. patents indicates that GPCR polynucleotides have utility and that such utilities were sufficiently specific and substantial to warrant the issuance of U.S. patents directed to methods used to identify and characterize GPCRs. Applicant states that the teachings of the patentable disclosures are directly applicable to the present

invention and are evidence that those skilled in the art recognize the specific and substantial utility of GPCRs.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, the current rejection is in compliance with the most currently-published version of the Utility Guidelines which require that all biological inventions must have credible, specific and substantial ("real world") utility. Additionally, each Patent Application is examined on its own merits. The invention that was deemed allowable in one patent has no bearing on this application.

(iv) At pg 6 of the Response, Applicant contends that the sequences of the present invention which encode a human G protein coupled receptor, olfactory receptor 2B6, have a utility that is recognized by those of skill in the art. Applicant indicates that this situation is similar to Example 10 of the PTO's Revised Interim Utility Guidelines Training Materials (pg 53-55). However, Example 10 is inapposite to the facts of the instant case. Unlike the DNA ligases shown in Example 10, which have a well-established use in ligating DNA, here the nucleic acids encode a polypeptide for which there is not a well-established use. Applicant attempts to establish a use for the encoded polypeptide by claiming it is highly homologous to a protein reported in the art to be an olfactory receptor, but that function is not demonstrated, and additionally, that function was not well-established at the time of filing of the instant application.

(v) At page 7-9 of the Response, Applicant argues that evidence of the "real world" substantial utility of the present invention is provided by the fact that there is an entire industry

established based on the use of gene sequences or fragments thereof in a gene chip format. Applicant submits that the "real world" substantial industrial utility of gene sequences or fragments would appear to be widespread and well established. Applicant contends that knowledge of the exact function or role of the presently claimed sequence is not required to track expression patterns using a DNA chip. Applicant states that compositions that enhance the utility of DNA chips, such as the presently claimed sequences, must in themselves be useful. Applicant contends that the presently described human olfactory receptor 2B6, provides unique specific sequence resources for identifying and quantifying full length transcripts that were encoded by the corresponding human genomic locus

Applicant's arguments have been fully considered but are not found to be persuasive. The asserted utility of assessing gene expression via DNA chips with the claimed polynucleotides is credible but not specific or substantial. Such can be performed for any polynucleotide. Further, the specification does not disclose any specific nucleic acid sequences used to generate the gene chip. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. Although Applicant indicates that the sequences in the instant specification (SEQ ID NOs: 1 and 2) are specific markers of the human genome, the specification does not teach if the entire sequences are to be used as markers or sections thereof. Additionally, one skilled in the art would not readily use the claimed nucleotide sequence of SEQ ID NO: 1 to make protein to be used for, for example, tissue-typing, in a real world sense since the protein is not specific to one tissue and is not associated with any disease or disorder. Also, evidence of mere expression in a cell or tissue is not tantamount to a showing of a role in any human diseases. There is also no disclosure that

the claimed polynucleotide encoding the NGPCR polypeptide is expressed at altered levels or forms in any specific, diseased tissue or cell relative to control healthy tissue or cell. Therefore, the skilled artisan would not know how to make and/or use the claimed invention in its full scope.

(vi) Applicant also argues at the top of pg 9 that the utility of the claimed polynucleotide in the pharmaceutical industry is bolstered by the expression of the sequences in the prostate. Applicant submits that the claimed polynucleotide could be used in an array for screening purposes.

Applicant's arguments have been fully considered but are not found to be persuasive. First, the specification indicates that the claimed NGPCR polynucleotide is expressed in more than one tissue, namely human brain, cerebellum, spinal cord, thymus, spleen, bone marrow, liver, placenta, prostate, thyroid, testis, adrenal gland, stomach, small intestine, colon, esophagus, bladder, rectum, pericardium, fetal lung, and gene trapped human cells (pg 7, lines 7-12). The asserted patentable utility of screening for the claimed polynucleotide is not substantial because one skilled in the art would not readily use the nucleotide sequences in a real world sense since the NGPCR polynucleotide or polypeptide is not specific to one tissue and is not associated with any disease or disorder. Furthermore, this asserted utility is not specific because numerous unrelated nucleotide sequences would also show a similar tissue typing pattern. Also, evidence of mere expression in a tissue is not tantamount to a showing of a role in a disorder.

The use of the claimed polypeptide in an array for selectivity screening is only useful in the sense that the information that is gained from the array is dependent on the pattern derived

from the array, and says nothing with regard to each individual member of the array. Again, this is a utility that would apply to virtually ever member of a general class of materials, such as any collection of DNA. Even if the expression of Applicant's individual polynucleotide is affected by a test compound in an array for drug screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. Given this consideration, the individually claimed polynucleotide has no "well-established" use. The artisan is required to perform further experimentation on the claimed material itself in order to determine to what use any expression information regarding this polynucleotide could be put. Any nucleotide sequence can be put on a DNA array and then this array can be screened to determine whether the expression pattern correlates with a disease state or condition. This is not a specific utility for this nucleic acid. A specific utility for this nucleic acid would be a correlation between expression of the specific nucleic acid in a disease state or some other condition which would be useful to know. That has not been demonstrated here.

It is further noted that the patents on batteries, automobile tires, golf balls, and treatments for a variety of human diseases are issued by the USPTO because the invention in each patent has a specific and substantial utility, not simply because the claimed subject matter is related to batteries, automobile tires, golf balls, or disease treatment. For example, a golf ball has a specific feature that makes the ball fly higher and further away as compared with other golf balls; a compound has a particular property that can be used to treat a specific disease, e.g., prostate cancer. It is not the case here.

(vii) Applicant further argues in the middle of pg 9 of the Response that the Examiner has confused the requirement for a specific utility with an alleged need for a "unique" utility. Applicant cites Carl Zeiss Stiftung v. Renishaw PLC, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991) which sets forth that "an invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications".

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, Carl Zeiss is inapposite to the facts of the instant case. In Carl Zeiss, the district court had found that a claim to a probe containing a stylus which is mounted to a movable arm above a table which supports an object to be measured lacked utility because "the arbitrary presentation of part of an invention does not constitute a claim of a valid invention" and that the claimed device could not function as a probe. See Carl Zeiss at 1180. In the instant case, however, the claims lack utility not because they are incomplete, and not because they do not set forth the best or only way to accomplish a result, and not because they are not unique, but because they do not have either a well-established utility or a specific and substantial asserted utility.

(viii) Beginning at the second paragraph of page 11 of the Response, Applicant argues that the claimed polynucleotide sequences have utility in localizing the specific region of the human chromosome and identification of functionally active intron/exon splice junctions. Applicant cites Venter et al. (Science 291: 1304) to allegedly demonstrate the significance of expressed sequence information in the structural analysis of genomic data.

This has been fully considered but is not deemed to be persuasive because such a utility is considered a research utility only designed to identify a particular function of the claimed sequences and is not a substantial utility. See, e.g., Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility." While the Examiner agrees with the Applicant on the scientific value of the claimed polynucleotide sequences and on the significance of expressed sequence information in structural analysis of genomic data, such a use of the polynucleotide sequences in gene mapping does not represent a specific and substantial utility. The exhibit and the publication cited by the Applicant merely show that the significance of expressed sequences in the structural analysis of genomic data; they do not show that the present polynucleotide sequences have a patentable utility.

(ix) Beginning at the third paragraph of pg 11 of the Response, Applicant summarizes case law on the utility requirement. Citing case law, Applicant urges that the present claims clearly meet the requirement of 35 U.S.C. §101. The essential disagreement appears to be the interpretation of what constitutes a specific, substantial and credible utility.

Applicant's arguments have been fully considered but are not deemed to be persuasive for the following reasons. First, the statement, "(t)o violate §101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401 (Fed. Cir. 1992), indicates that a rejection under 35 U.S.C. § 101 *for lack of operability* can be overcome by a showing of actual use or commercial success. The claimed invention in the instant case is drawn to nucleic acid sequences, not a device; the instant rejection under 35U.S.C. §101 is not directed to inoperativeness of a device,

rather to a lack of patentable utility of the claimed nucleic acid sequences; and the instant issue is whether the asserted utilities meet the three-pronged test for a patentable utility.

Secondly, since the specification fails to disclose a specific, substantial utility or a well-established utility, the present claims do not satisfy the utility requirement of 35 U.S.C. §101. Merely citing case laws on the utility requirement does not render a patentable utility for the present invention. While "anything under the sun that is made by man" is patentable, it does not necessarily mean the present invention is patentable. In fact, the present invention is not patentable due to lack of a patentable utility.

Furthermore, while the FDA approval is not a prerequisite for finding a compound useful within the meaning of the patent laws, and the requirement for the utility of the claimed invention is different from the FDA standard for drug approval, 35 U.S.C. §101 does require a specific, substantial, and credible utility, or well-established utility for an invention. Such a utility has to be a "real world " context of use which does not require significant further research. Applicant confuses this requirement with the "further research and development" needed in pharmaceutical composition and drug development. In other words, a patentable utility has to be clearly identified or immediately apparent in the specification, whereas some "further research and development" is permitted in drug development. For example, determining optimal dosages or drug tolerance in human is further research and development, which is acceptable under 35 USC §101 because it is not significant. On the other hand, determining a specific disease to be treated by a drug constitutes significant further research and development, which is not acceptable under 35 U.S.C. §101.

In the instant case, the specification fails to disclose the biological functions, physiological significance, or any specific and substantial utility of the claimed molecules. Without such information, how can one in the skilled art use the claimed invention in a meaningful manner? See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

(x) Finally, at page13-14 of the Response, Applicant, challenges the legality of the Patent Examination Utility Guidelines and the validity of issued US patents. It is noted that an Examiner has no authority to comment on the legality of the Guidelines and the validity of US Patents.

2. Claims 3-9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The basis for this rejection is set forth at pg 11 of the Office Action of 23 October 2002 and the Office Action of 13 March 2002.

Please see arguments above.

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

BEB
Art Unit 1647
09 March 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER